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Wrong SIGN, NICE mess: is national guidance distorting allocation of resources?

Richard Cookson, David McDaid, Alan Maynard

The Scots and the English and Welsh are producing national guidance on NHS practice in different ways. Two apparently competing national agencies have already been established in Scotland—the Health Technology Board for Scotland and the Scottish Intercollegiate Guidelines Network (SIGN). Yet another one is in the pipeline—the Scottish Medicines Consortium. In England and Wales there is one agency—the National Institute for Clinical Excellence (NICE). Are these national agencies contributing effectively to the enhancement of performance in the NHS or are they merely fuelling demand and distorting the processes by which resources are prioritised?

Wrong SIGN

SIGN's objective is "to improve the quality of health care for patients in Scotland by reducing variation in practice and outcome, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence."¹ SIGN has been reluctant to consider resource issues,² and economic considerations have been limited to some "back of the envelope" calculations about the budgetary impact of, for example, antibiotic prophylaxis for surgery.³

This approach may help to reduce clinical error and, at best, may help to reduce variations in practice for recommendations that are easily affordable by local NHS bodies. It does little to reduce variations for more costly recommendations or to aid transparency in allocation of resources. If SIGN does not take careful account of cost, then local cash constrained NHS bodies certainly will. Any costly recommendations issued by SIGN will therefore be followed or ignored at a local level largely on the basis of behind the scenes power politics, free from public scrutiny and debate about what alternative services could have been purchased.

The approach taken by SIGN does nothing at all to increase efficiency in the allocation of resources. Being efficient is not the same thing as being cheap. An intervention may be relatively costly yet relatively efficient—that is, it may do more good per pound spent than other, relatively cheaper, interventions—and vice versa. To improve efficiency decision makers need information on what economists call opportunity costs—the benefits foregone when scarce resources are used one way rather than another. With this information, efficiency can be improved by reallocating resources towards relatively cost effective interventions and away from less cost effective ones, thus delivering greater health gains for the same level of spending. Of course decision makers may be interested in the efficient delivery of benefits other than health gains, taking account of local circumstances such as budgetary impact and wider political and ethical considerations. In the absence of any information about opportunity

Summary points

The Scottish Intercollegiate Guidelines Network, a precursor to the National Institute for Clinical Excellence (NICE) in England and Wales, has not yet started to consider cost effectiveness

NICE considers cost effectiveness but has been reluctant to advise against funding many costly new pharmaceuticals in the NHS in England and Wales

NICE must devise politically acceptable ways of refusing to spend taxpayers' money on costly new drugs and devices that lack demonstrable incremental cost effectiveness

Otherwise, new and often inefficient technologies will continue to fuel the widening gap between public expectations and public willingness to pay for the NHS

NICE should prioritise new national guidance within a fixed growth budget for the net cost of new technologies and in relation to incremental cost effectiveness

If reducing postcode rationing would compromise more important goals of equity or efficiency, NICE should sometimes refuse to issue definite national guidance

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cost, however, they cannot attempt to achieve the efficient use of resources.

These elementary economic principles have been carefully and clearly set out in many introductory texts on economic evaluation in health care.⁴ So either SIGN's protagonists believe that efficiency is an irrelevant objective or they have failed to understand the logic of resource allocation. Either way, SIGN is inadequate because seemingly robust professional advice is distributed to clinicians, which, if adopted, will distort resource allocation and waste scarce resources.

SIGN's rival or complementary organisation (why is there such an overlap in such a small country?) is the Health Technology Board for Scotland. This is charged with "providing a single Scottish source of advice on the clinical and cost-effectiveness of new and existing health technologies."⁵ The board is now over a year old, but it has faced difficulties recruiting staff and seems fated to contract out its work. Whether it does its work "in house" or outside in academia or in commercial agencies, the board is confronted by gross deficiencies in the supply of well trained health service researchers and health economists. Unfortunately, the board seems stymied at



birth, while local politicians and policymakers are increasingly impatient about the production of “results.”

There are plans to launch yet another agency in Scotland later in 2001—a consortium of local area drug and therapeutics committees (Health Technology Board for Scotland, personal communication, 2001). This new Scottish Medicines Consortium will provide national guidance to local health boards and prescribers on whether new drugs should be adopted. It is difficult to see how this new body will be able to give careful consideration to cost effectiveness, as distinct from budgetary impact. It is even harder to see how this sudden proliferation of overlapping NHS advisory bodies in Scotland can further the cause of transparency and efficiency in resource allocation.

NICE mess

In England and Wales, NICE produces national guidance on individual technologies (“appraisals”), the management of specific conditions (“clinical guidelines”), and clinical audit.⁶ The purpose of this guidance is to assist health professionals in providing NHS patients with the highest attainable level of care. In pursuing this goal NICE must ensure that its advice is based on rigorous analysis and assessment of all the available evidence and encompasses both clinical effectiveness and cost effectiveness.⁷

In pursuing this ambitious agenda, NICE has an inadequate budget and, until recently, a less than transparent evaluation process. Thus the eventual decision of NICE to support the use of zanamivir in the NHS was based on evidence that was not available to outsiders until three weeks after the decision was announced. Consequently, many people were dubious about the scientific basis of this decision and some have subsequently over-ridden it.⁸ Similar concerns have been expressed about some other decisions (for example, on taxanes) and delayed decision making (for example, about interferon beta for multiple sclerosis) by NICE.^{9–10} Since April 2001 all evidence has had to be open, and this welcome change will aid transparency. However, the continued and protracted lobbying of NICE by patients’ organisations and industry bodies generates fears that decisions can and will continue to be delayed by mechanisms other than the evidence base.

These are not the only problems with NICE. The decisions of NICE are not mandatory but advisory: the

chairman of NICE, Sir Michael Rawlins, has declared their purpose to be to give “guidance” to professionals.¹¹ Legally, guidance cannot be mandatory: the 1948 and subsequent NHS acts stipulate that the NHS cannot require individual clinicians to practise medicine in any particular way. However, the NHS tends to react as if advice from NICE were mandatory, as do the media. One exception to this has been a group of general practitioners in north Devon who robustly rejected NICE’s advice on zanamivir.¹²

NICE has concluded that all of the new pharmaceuticals it has appraised are cost effective and has refused to rank them in any form of hierarchy—not even a grading of “high,” “medium,” or “low” cost effectiveness, let alone a full scale league table. As a consequence, health authorities are slavishly funding marginally cost effective drugs approved by NICE and diverting funding away from more cost effective existing services that lack politically powerful advocates (for example, hip replacements and cataract surgery). NICE has effectively become an advocacy mechanism by which lobbies of specialists and their supporters in the pharmaceutical industry extract more public money from the NHS. Instead of challenging the pharmaceutical industry to show value for money, NICE has become their “golden goose.”

There are also concerns about equity. NICE places heavy emphasis on reducing “postcode prescribing” of interventions.¹³ With fixed budgets, however, NICE guidance that is adopted will be funded by cutting (or by diluting, delaying, deterring, or deflecting) other services. Local decisions about such cuts will vary. As a consequence, geographical variations in quality of care may actually increase for those less fortunate services bereft of attention from NICE. Worse, the focus on postcode prescribing may divert attention from other goals relating to equity. For example, individual patients from the professional classes may prove particularly adept at insisting that NICE guidance is followed in their particular cases. This might exacerbate inequalities in access to high quality health care.

The way forward

To remedy these problems, NICE needs to become a national healthcare rationing agency, and SIGN and the other Scottish agencies should complement this activity. Firstly, NICE needs to start saying “no” to costly and relatively cost ineffective new drugs and devices. Rationing of new technologies is essential for political as well as economic reasons. Without politically acceptable ways of doing this, technology will continue to fuel the widening gap between public expectations and public willingness to pay for the NHS. The wider this gap grows the greater the risk that wealthier patients will turn to the private sector for their core health services, leading ultimately to the NHS becoming a rump service used only by the poor and the unhealthy.

To ensure consistency in decisions on rationing made by NICE, a fixed growth budget for new technologies might be implemented (over, say, a three year cycle), within which NICE must prioritise its guidance. This could be distributed to health authorities and primary care trusts in proportion to the estimated net costs of the new technologies, and could cover all NHS and associated social care costs for each technol-

ogy over a particular time period. It could also account for savings resulting from guidance on stopping the use of established technologies, giving NICE an incentive to identify disinvestment opportunities (for example, induction of labour using vaginal gel rather than cheaper but equally effective vaginal tablets¹⁴). To preserve incentives for realistic estimation of net costs, local bodies could be allowed to demand further cash from NICE if they can show after the event that the original estimates by NICE were too low.

A second change would be for NICE to be given the option of concluding that definite national guidance is inappropriate for some technologies, if reducing postcode prescribing would compromise other goals relating to equity or efficiency. A case in point might be interferon beta for multiple sclerosis—positive guidance might not be cost effective (yielding modest benefits to a relatively small number of patients at a high total cost), but negative guidance might compromise the NHS principle of seeking to do as much as possible for seriously ill patients. Leaving funding decisions to local discretion might be the best option.

As an aid to decision making, NICE should publish information on cost effectiveness in a format that makes it readily comparable across appraised technologies, including league tables of incremental cost effectiveness whenever possible. Such tables might provide information on cost effectiveness for different subgroups of the population, differentiate between local and overseas data, and grade the quality of these data on the basis of compliance with guidance on methods published by NICE.¹⁵

A final proposal is to develop price-performance contracts, which would allow costly new technologies to be funded on condition that the future price is linked to the performance of the product in further industry sponsored clinical trials or observational studies of the technology in routine use. Evidence of improved cost effectiveness might lead to higher product prices and vice versa. If such binding price-performance agreements could be implemented, this would reduce the political pressure on NICE to give an unconditional acceptance at the launch of a product, before good information about cost effectiveness becomes available. Contracting would ensure that, if new data show that actual cost effectiveness differs from that promised at launch, companies would have to adjust the price to maintain the promised level of cost effectiveness.

Conclusion

There seems to be little appreciation of the economic issues surrounding both the wrong SIGN and the NICE mess. Such issues are complicated by the imprecise knowledge base for informing analysis of clinical effectiveness and cost effectiveness, the comparative advantage of the healthcare industry in “creatively cultivating” or biasing trial results, and the difficulty of incorporating equity factors into explicit and evidence based methods of assessing health technology.

Without doubt it is wise to invest in health technology assessment in a complementary manner within the United Kingdom. Appropriate orientation in terms of transparency and efficiency of resource allocation

seems less than complete: neither SIGN nor NICE is performing its function of informing “hard choices” about the rationing of scarce healthcare resources.¹⁶ As protagonists vie for shares of this new “healthcare feast,” the concern must be that the direction of these organisations is muddled and not likely to ensure efficient and equitable use of society’s scarce resources. This muddle is, in part, the responsibility of naive and over ambitious politicians who promise more than can reasonably be delivered; it is also partly the responsibility of practitioners in these organisations.

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Endpiece

Beyond the blame culture?

You cannot separate the just from the unjust and
the good from the wicked;
For they stand together before the face of the sun
even as the black thread and the white are woven
together.
And when the black thread breaks, the weaver shall
look into the whole cloth and he shall examine the
loom also.

The Prophet, Kahlil Gibran
(a Lebanese poet), 1923

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